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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,006	07/24/2001	Donald Shannon	VAS-4761CONDIV	5855

7590 11/24/2003  
Edwards Lifesciences LLC  
Law Dept.  
One Edwards Way  
Irvine, CA 92614

EXAMINER
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ROSSI, JESSICA

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 11/24/2003

160

Please find below and/or attached an Office communication concerning this application or proceeding.

C2016

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/912,006	SHANNON ET AL.	
	Examiner	Art Unit	
	Jessica L. Rossi	1733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/14/03, Amendment E.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23,24,27,29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,24,27,29 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Request for Continued Examination***

1. The request filed on 9/2/03 for a RCE under 37 CFR 1.114 based on parent Application No. 09/912,006 is acceptable and a RCE has been established. An action on the RCE follows.

***Response to Amendment***

2. The action is in response to the amendment dated 10/14/03. Claims 25-26, 28, and 30-31 were canceled. Claims 23-24, 27, 29, and 32 are pending.

3. The rejection of claim 23 under 35 U.S.C. 102(b) as being anticipated by the Admitted Prior Art in the specification of the present application, as set forth in paragraph 8 of the previous office action, has been withdrawn in light of the present amendment.

4. The rejection of claims 24, 27, 29, and 32 under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of House et al. (of record), as set forth in paragraph 10 of the previous office action, has been withdrawn in light of Applicants present arguments.

5. The rejection of claims 23 and 24-32 under the doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34-35, and 41 of US patent 5,928,279 (of record), as set forth paragraphs 12 and 13 of the previous office action, has been withdrawn in light of Applicants arguments and the present amendment to the claims.

6. With respect to the present amendment, it is noted support can be found on p. 13, lines 25-29 of the specification.

***Priority***

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency is required.

Applicants claim that the present application is a division of US serial no. 09/201,953, filed on 12/1/98 and issued as US patent 6,267,834 on 7/31/01, which is a continuation of US serial no. 08/423,762, filed on 4/17/95 and issued as US patent 5,641,373 on 6/24/97. Since the '953 application was filed after the '373 patent issued, copendency never existed between these applications. Therefore, the **effective filing date of the present application is 12/1/98 and NOT 4/17/95.**

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 23-24, 27, 29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shannon et al. (US 5641373).

With respect to claim 23, Shannon is directed to a radially expandable tape-reinforced vascular graft. The reference teaches a tubular PTFE base graft and a reinforcing tape wrapped around the tubular base graft wherein the tape reinforced graft is capable of undergoing radial enlargement of greater than 5% to increase its diameter without breaking or tearing of the reinforcing tape (abstract; column 3, lines 46-49; column 4, line 29; column 5, lines 28-29; column 8, lines 53-54).

Regarding claim 24, the reference teaches the base graft comprising a sintered, longitudinally expanded PTFE extrudate (column 4, lines 10-11 and 20-21).

Regarding claim 27, the examiner points out that method steps get no weight in an article claim. However, it is noted that the reference teaches the base graft being longitudinally expanded by an expansion ratio of more than two to one (column 4, lines 16-18).

With respect to claim 29, the examiner points out that the method steps pertaining to the graft having been radially reduced in size from an expanded diameter to a reduced diameter and the tape being reduced in size from an expanded porosity to a reduced porosity get no weight in an article claim. Therefore, all the limitations were addressed above with respect to claim 23.

Regarding claim 32, all the limitations were addressed above with respect to claim 24.

10. Claims 23 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt (US 5527353).

*It is noted the present invention is directed to overcoming problems in the prior art relating to the radial expansion of PTFE tape-reinforced grafts. Applicants teach it is known in the prior art to make these reinforced grafts by expanding and sintering both the PTFE base graft and the PTFE tape, wherein the sintered tape makes it impossible for the graft to undergo radial expansion up to and beyond 5% of its diameter without breaking or tearing the tape (p. 1, line 22 - p. 2, line 13). Applicants overcome this problem by radially shrinking the tape and/or base graft prior to expansion.*

With respect to claim 23, Schmitt is directed to a radially expandable tape-reinforced vascular graft 10. The reference teaches a tubular PTFE base graft ("liner") 4 (Figure 1; column 4, lines 52-55; column 2, lines 57-60) and a reinforcing tape ("textile substrate") 2 wrapped about

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the base graft (column 3, lines 25-26; column 6, lines 11-13). The reference teaches the tape can be PTFE or other polymeric materials (column 5, lines 64-68; column 8, lines 7-10).

One reading the reference as a whole would have appreciated that the tape, when made from PTFE or other polymeric materials, is not expanded and therefore not sintered since the reference does not teach or suggest such and it is readily known in the graft art that PTFE materials are only sintered after they have been expanded. Therefore the skilled artisan would have appreciated that the graft of Schmitt would be capable of undergoing radial expansion of greater than 5% to increase its diameter without breaking or tearing the tape.

With respect to claim 29, the examiner points out that the method steps pertaining to the graft having been radially reduced in size from an expanded diameter to a reduced diameter and the tape being reduced in size from an expanded porosity to a reduced porosity get no weight in an article claim. Therefore, all the limitations were addressed above with respect to claim 23.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt and further in view of Calcote et al. (US 5453235).

Regarding claims 24 and 32, Applicants are directed to paragraph 10 above for a complete discussion of the Schmitt reference. Schmitt teaches the PTFE base graft being expanded PTFE but is silent as to it being a sintered, longitudinally expanded extrudate.

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The skilled artisan would have appreciated that it is notoriously well-known in the art that “expanded” PTFE graft materials have been expanded and then sintered to lock the crystalline structure of the PTFE in its expanded dimensions, as taught by Calcote (column 1, line 62 – column 2, line 5). Therefore, the skilled artisan would have appreciated that the “expanded” PTFE base graft of Schmitt is sintered.

As for the direction of this expansion and the PTFE being an extrudate, it would have been obvious to use a longitudinally expanded PTFE extrudate because such is known in the art, as taught by Calcote (column 3, lines 43-44), wherein such lends itself to good performance in the graft art.

13. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt and Calcote et al. as applied to claim 24 above and further in view of House et al. (US 5026513; of record).

Regarding claim 27, the examiner points out that method steps get no weight in an article claim. However, selection of a particular expansion ratio would have been within purview of the skilled artisan at the time the invention was made. Furthermore, it would have been obvious to use an expansion ratio of more than 2:1 because such is known in the art, as taught by House (column 6, lines 30-36).

#### ***Response to Arguments***

14. Applicant's arguments with respect to claims 23 and 29 have been considered but are moot in view of the new ground(s) of rejection.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **703-305-5419** (571-272-1223 come mid December). The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard D. Crispino can be reached on 703-308-3853. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

*Jessica L. Rossi*  
Jessica L. Rossi  
Patent Examiner  
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